REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This amendment is filed concurrently with a request for continued examination in lieu of filing an Appeal Brief in response to the Notice and the Office Action.

The Office Action rejected claims 1-19 under 35 USC §103 as unpatentable over United States Patent No. 5,456,851 to Liu ("Liu"), United States Patent No. 5,536,742 to Mason, ('Mason'), individually or in combination, and further in combination with United States patent No.: 5,688,496 to Fost ("Fost '496"), United States Patent No. 5,648,348 (Fost '348"), and United States Patent No. 5,164,375 to Vanmiddlesworth ('Vanmiddlesworth"). Claims 2 and 16 were cancelled. Claims 20-23 were added. Claims 1, 3-15, and 17-23 remain pending in the application after entry of this amendment.

Claim 1 and claim 6 were amended by inserting the subject matter of dependent claim 3 into both claims. Claim 3 was amended to incorporate the language of claim 1 and claim 2 therein. Claims 2 and 16 were cancelled. Newly added claims 20 to 22 are directed to subject matter found in original claims 4 – 6, but are dependent upon claim 3. Newly added claim 23 is directed to subject matter found in original claims 1 and 4 and in Example 7 of the Specification on page 13, line 12 to page 15, last line; accordingly, claims 20 - 23 do not introduce new matter into the application under 37 CFR 1.121.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned, "Version with markings to show changes made."

The Rejection of Claims 1 – 19 under 35 USC §103(a) as Being Unpatentable Over Liu and/or Mason, and Further Over Fost '496, Fost '348, or Vanmiddlesworth Should Be Withdrawn



Claims 1 – 19 stand rejected under 35 USC §103(a) as being unpatentable over Liu and/or Mason individually or in combination, further in combination with Fost '496, Fost '348, or -Vanmiddlesworth._Applicants respectfully disagree for the reasons that follow.

As stated in the Office Action, Liu and Mason neither disclose nor suggest the use-of-phospholipids. Therefore, Applicants further respectfully submit that neither Liu nor Mason disclose or suggest the use of the <u>particular</u> antifungal amphoteric phospholipids as claimed in claim 1, claim 3, and claim 6.

Moreover, neither of the Fost references nor Vanmiddlesworth discloses the <u>particular</u> antifungal amphoteric phospholipid as specifically claimed in claims 1, 3 and 6. Therefore, Applicants respectfully submit that the composition that would result from combining the phospholipids of either Fost reference or Vanmiddlesworth with the anti-fungal containing compositions of Liu and Mason as proposed in the Office Action still would not meet the terms of claim 1. More specifically, the resulting combination would still lack the particular antifungal phospholipid as specifically claimed in claims 1, 3, and 6. For example, the phospholipids of the Fost references lack the acyl group present in the claimed phospholipid.

As recognized in Fost '348 itself, not all phospholipids are capable of exhibiting antimicrobial properties without also being extremely irritating to the skin. See Fost '348, column 1, lines 23 – 51. Therefore, absent any other disclosure or suggestion in the art, Applicants respectfully submit that one skilled in the art would not know that the particular phospholipid as claimed would provide effective antifungal properties without the undesirable irritation properties when used in combination with the antifungal "inhibiting fungal ergosterol biosynthesis" ingredient in a cleansing composition.

In view of the above, Applicants respectfully submit that claim 1, claim 3, and claim 6 are patentable over Mason and/or Liu and further in combination with Fost '496, Fost '348, and Vanmiddlesworth, and that the rejection of claim 1 and claim 6 under 35 USC §103(a) has been overcome and should be withdrawn.

Claims 4-5, 14, and 19, which depend upon claim 1 and incorporate all its limitations therein, and claims 7 — 15 and 17 - 18 which depend upon claim 6 and incorporate all of its limitations therein, are likewise patentable over Mason and/or Liu and further in combination with Fost '496, Fost '348, and Vanmiddlesworth, and that the rejection of these claims under 35 USC §103(a) has also been overcome and should be withdrawn.

In view of the fact that Applicants unexpectedly found that the claimed active ingredients unexpectedly possessed a synergistic effect on the growth of *M. furfur*, Applicants respectfully

submit that none of the cited references disclose or suggest the creation of a composition containing the claimed active ingredients in quantities producing "a mutual synergistic effect on the inhibition of the growth of Malassezia furfur" as claimed in claim 4.

Because none of the references disclosed the combination of the claimed antifungal—with the claimed amphoteric phospholipid, let alone the above mentioned synergistic effect exhibited by such a combination, Applicants further respectfully submit that none of the prior art references disclose or suggest the percentage amount of each claimed component as set forth in claim 5.

In addition, in view of the fact that none of the prior art references disclosed or suggested the claimed composition of claim 1, Applicants further respectfully submit that the process for making such a composition set forth in claim 14 is also neither disclosed nor suggested in the prior art.

In view of the cancellation of claims 2 and 16, the arguments set forth above for claim 1, claim 3, and claim 6, and the additional arguments set forth above for the dependent claims, Applicants further respectfully submit that the rejection of claims 1 to 19 under 35 USC §103(a) has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

By:

Michele G. Mangini (Attorney for Appliquents)

Reg. No. 36,806

Dated: Dated 2003

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2810 JAB 1267amt.rce

Version with Markings to Show Changes Made

IN THE CLAIMS:

Claims 2 and 16 have been cancelled.

The claims have been amended as follows:

(Four Times Amended) A body or hair cleansing composition comprising
 (a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active

ingredient,

(a-2) a amphoteric phospholipid as a second antifungal active ingredient, wherein the phospholipid has the formula

$$\begin{pmatrix}
H & CH_3 & OH \\
R & N & N & OH \\
O & CH_3 & OH
\end{pmatrix}_{X} + x Cf$$

Wherein R represents a straight, saturated, mono-unsaturated, or poly-unsaturated C7-19 alkyl group; x represents 1, 2, or 3; and x+y = 3; and mixtures thereof;

and

(b) at least one surfactant other than a phospholipid.

3. (Amended) A composition [according to claim 2] comprising

(a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active ingredient, wherein the antifungal inhibiting fungal ergosteriol biosynthesis is an azole selected from the group comprising ketoconazole, econazole, elubiol, miconazole, itraconazole, fluconazole, or a mixture thereof, or is an allylamine selected from the group comprising terbinafine, naftifine, or a mixture thereof,

(a-2) a synthetic amphoteric phospholipid as a second active antifungal ingredient, wherein the phospholipid has the formula

$$\begin{bmatrix}
H & CH_3 & OH \\
N & V & CH_3
\end{bmatrix}$$

$$\downarrow P & C & CH_3$$

$$\downarrow Q & CH_3$$

Wherein R represents a straight, saturated, mono-unsaturated, or poly-unsaturated C7-19 alkyl group; x represents 1, 2, or 3; and x+y = 3; and mixtures thereof; , and

(b) a carrier.

6. (Four Times Amended) A composition comprising

(a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active ingredient,

(a-2) a amphoteric phospholipid as a second antifungal active ingredient, wherein the phospholipid has the formula

$$\begin{pmatrix}
H & CH_3 & OH \\
N & N & OH \\
CH_3 & OH
\end{pmatrix}_{X} + x Cf$$

Wherein R represents a straight, saturated, mono-unsaturated, or poly-unsaturated C7-19 alkyl group; x represents 1, 2, or 3; and x+y = 3; and mixtures thereof; and

(b) at least one surfactant, wherein said composition is formulated as a shampoo.

The following claims have been added:

- --20. (New) A composition according to claim 3 formulated as a shampoo.--
- --21. (New) The composition according to claim 3 wherein the first and the second active ingredients are present in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*.--
- --22. (New) The composition of claim 3 wherein the first active ingredient is present in an amount ranging from about 0.1 % to about 2% (w/w) and the second active ingredient is present in an amount ranging from about 0.04% to about 10% (w/w), the amount of the latter being expressed as weight of phospholipid.--
- --23. (New) The composition of claim 3 wherein the first active ingredient is ketoconazole, and the second active ingredient is cocamidopropylphosphatidyl PG-dimonium choloride, and wherein the first and the second active ingredients are present in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*.--